**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**
k042151

**B. Purpose for Submission:**
New device

**C. Analyte:**
Human chorionic gonadotropin

**D. Type of Test:**
Qualitative

**E. Applicant:**
Acon Laboratories, Inc.

**F. Proprietary and Established Names:**
ACON SPECTRUM hCG Midstream Pregnancy Test

**G. Regulatory Information:**

1. Regulation section:
   21 CFR 862.1155
2. Classification:
   II
3. Product Code:
   LCX
4. Panel:
   75

**H. Intended Use:**

1. Intended use(s):
   The ACON SPECTRUM hCG Midstream Pregnancy Test is intended for the qualitative identification of the elevated level of human chorionic gonadotropin (hCG) in urine to aid in the determination of pregnancy. It is for over-the-counter consumer use.
2. Indication(s) for use:
   The ACON SPECTRUM hCG Midstream Pregnancy Test is intended for the qualitative identification of the elevated level of human chorionic gonadotropin (hCG) in urine to aid in the determination of pregnancy. It is for over-the-counter consumer use.
3. Special condition for use statement(s):
   The device is for over-the-counter use.
4. Special instrument requirements:
   Not applicable

**I. Device Description:**
The device is a test wand with a fiber tip on one end and a plastic casing on the other end. The test contains mouse monoclonal antibody conjugated with a proprietary dye-binding system and goat polyclonal antibody. The test is supplied sealed in a foil pouch in 1-test and 2-test kit formats.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):
   ACON Midstream Pregnancy Test
2. Predicate K number(s):
   k983090
3. Comparison with predicate:

| Similarities | | |
|---|---|---|
| **Item** | **Device** | **Predicate** |
| Intended Use/ Indications for Use | For over-the-counter use for the qualitative identification of hCG in urine to aid in the determination of pregnancy | Same |
| Detection limit | 25 mIU/mL | Same |
| **Differences** | | |
| **Item** | **Device** | **Predicate** |
| Methodology | Dye-binding membrane immunoassay | Particle membrane immunoassay |

**K. Standard/Guidance Document Referenced (if applicable):**

None referenced

**L. Test Principle:**

The test is a membrane immunoassay in which an antibody-antigen-antibody sandwich is formed.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:
   - *a. Precision/Reproducibility:*
     A retrospective focus group study on reproducibility was conducted using the ACON SPECTRUM hCG Midstream Pregnancy Test. Urine samples from male donors spiked to hCG concentrations of 10, 25, and 100 mIU/mL (standardized to the World Health Organization Fourth International Standard for Chorionic Gonadotropin [WHO $4^{th}$ I.S.]) along with unspiked samples (0 mIU/mL) were coded and blind-labeled for testing. One hundred and twelve (112) female study participants each tested four coded samples on both the predicate device and the new device. The results were as follows: 99% (111/112) of the participants obtained a positive result for the samples containing 25 mIU/mL hCG, and 100% of the participants obtained a negative result for samples containing 0 mIU/mL hCG and a positive result for samples containing 100 mIU/mL.
   - *b. Linearity/assay reportable range:*
     Not applicable
   - *c. Traceability (controls, calibrators, or method):*
     WHO $4^{th}$ I.S.

d. *Detection limit:*
The detection limit is 25 mIU/mL. See "Reproducibility/Precision" above for more information.

e. *Analytical specificity:*
Homologous hormones, drugs and urine analytes (urine pH, and specific gravity) were all evaluated for potential interference in the assay.

Luteinizing hormone (LH 300 mIU/mL), follicle stimulating hormone (1,000 mIU/mL), and thyroid stimulating hormone (1,000 µIU/mL) were spiked separately into urine samples containing 0 mIU/mL hCG and 25 mIU/mL hCG standardized to the WHO 4$^{th}$ International Standard. These samples were tested with the ACON SPECTRUM hCG Midstream Pregnancy Test in triplicate with visual interpretations scored at three and ten minutes after urine application. None of the negative samples spiked with LH, FSH, and TSH yielded a positive result when tested with the pregnancy test. Similarly, none of the hCG positive urine samples spiked with LH, FSH, and TSH yielded a negative result.

Various prescription and over-the-counter drugs and common urine analytes were spiked into urine pools containing either 0 mIU/mL or 25 mIU/mL hCG. The spiked samples were tested with three lots of the ACON SPECTRUM hCG Midstream Pregnancy Test in triplicate with visual interpretations made at three and ten minutes after sample application. None of the potential interfering substances, at the concentrations tested, interfered with the expected positive or negative hCG results.

A neat urine pool was aliquoted into five test tubes, and the pH of these samples was adjusted within the range of 5 to 9. The pH-adjusted urine sample was split into two aliquots, and one aliquot was spiked with hCG to 25 mIU/mL. All pH-adjusted urine samples were tested in duplicate and read at three and ten minutes after sample application. The urine pH, ranging from 5 to 9, did not interfere with the performance of the ACON SPECTRUM hCG Midstream Pregnancy Test. Correct positive and negative results were obtained at all pH levels.

Fifteen urine samples (from males) with specific gravity ranging between 1.001 and 1.046 were aliquoted into three parts: one remained as neat urine, one part spiked to 25 mIU/mL hCG, and one part spiked to 100 mIU/mL. All samples were tested on three lots per level of hCG, with the results read at three and ten minutes after sample application. The specific gravity of the urine samples did not interfere with the performance of the ACON SPECTRUM hCG

Midstream Pregnancy Test. Correct positive and negative results were obtained at all specific gravity levels.

*f. Assay cut-off:*
See "Detection limit" above.

2. Comparison studies:
   *a. Method comparison with predicate device:*
   The ACON SPECTRUM hCG Midstream Pregnancy Test was compared to the ACON hCG Midstream Pregnancy Test (predicate) using spiked and natural urine samples totalling over 200. In both cases the results demonstrated agreement. See "Precision/Reproducibility" above and "Other clinical supportive data" below for more information.
   *b. Matrix comparison:*
   Not applicable
3. Clinical studies:
   *a. Clinical sensitivity:*
   Not applicable
   *b. Clinical specificity:*
   Not applicable
   *c. Other clinical supportive data (when a and b are not applicable):*
   A consumer field study using 119 women (mostly who suspected pregnancy and some who were known pregnant) was conducted. The women were asked to perform the new test following the package insert instructions and to donate urine samples to the lab for confirmation of their test results. After the consumers finished testing, they recorded the test result on a data sheet and filled out a questionnaire. The urine samples provided to the lab were coded and blind-tested. Seventy-six (76) positive and forty-three (43) negative results were obtained on the new and predicate test. The results demonstrated an accuracy of over 99% when compared to the ACON Midstream Pregnancy Test (predicate). Additionally, the results showed that the consumers found the test very easy to use and that they had no trouble understanding the labeling and interpreting the results.
4. Clinical cut-off:
   Not applicable
5. Expected values/Reference range:
   The expected values are based on literature.

**N. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.